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(19) (CA) **APPLICATION FOR CANADIAN PATENT** (12)

(54) Dosing Apparatus for Sterile and/or Pharmaceutical
Solutions

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(57) 6 Claims

Notice: This application is as filed and may therefore contain an
incomplete specification.

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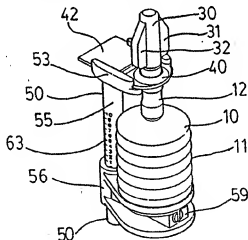
PCT
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<p>(51) Clasificación Internacional de Patentes⁸ : G01F 11/08, A61M 5/28, 5/315</p>	<p>A1</p>	<p>(11) Número de publicación internacional: WO 93/10422</p> <p>(43) Fecha de publicación internacional: 27 de mayo de 1993 (27.05.93)</p> <p style="text-align: center; font-size: 1.2em; font-weight: bold;">2101049</p> <p>(21) Solicitud Internacional: PCT/ES91/00081</p> <p>(22) Fecha de presentación internacional: 22 de noviembre de 1991 (22.11.91)</p> <p>(71) Solicitante (para todos los Estados designados salvo US): INDUSTRIAS PALEX, S.A. (ES/ES); Joan Sebastià Bach, 12, E-08021 Barcelona (ES).</p> <p>(72) Inventor; e</p> <p>(75) Inventor/solicitante (sólo US) : CASAMIRA CAMPS, Pedro (ES/ES); Pare Llauredó, 128, E-08224 Barcelona (ES).</p> <p>(74) Mandatario: TORNER LASALLE, Núria; Alberes, 2, E-08017 Barcelona (ES).</p> <p>(81) Estados designados: AU, BR, BG, BR, CA, FI, HU, JP, KP, KR, LK, MC, MG, MW, NO, PL, RO, SD, SU, US, Patente europea (AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LU, NL, SE), Patente OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG).</p> <p>Publicada Con informe de búsqueda internacional.</p>
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(54) Title: DOSING APPARATUS FOR STERILE AND/OR PHARMACEUTICAL SOLUTIONS

(54) Título: DISPOSITIVO DOSIFICADOR DE SOLUCIONES ESTERILES Y/O FARMACEUTICAS



(57) Abstract

The dosing device for sterile and/or pharmaceutical solutions is comprised of a laminar body (10) which contains the solution, presenting a top neck wherein a tubular nozzle (20) may be inserted and which is covered by a cup (30) having a weakened area, with a fluted ring (40) which interconnects said parts. The device may be coupled to a rigid support (50) which has a base slidable on an axis in order to apply the solution by manually pressing on the base of said support.

(57) Resumen

El dispositivo dosificador de soluciones estériles y/o farmacéuticas objeto de la actual invención está formado por un cuerpo laminar (10) que contiene la solución, presentando un cuello superior en el interior del cual es insertable una boquilla tubular (20) que queda cubierta por un capuchón (30) que presenta una zona debilitada, con un anillo acanalado (40) que mantiene unidas entre sí las partes señaladas. El dispositivo es acoplable a un soporte rígido (50) que comprende una base deslizante sobre un eje que permite aplicar la solución a través de una presión manual sobre la base de dicho soporte.

DOSING APPARATUS FOR STERILE AND/OR
PHARMACEUTICAL SOLUTIONS

The present invention relates to a dosing apparatus
5 for sterile and/or pharmaceutical solutions, comprised of a
disposable container which contains the solution, provided
with a nozzle with a cup, a sealing ring and a rigid support
for holding the assembly, which, in its turn, makes the use
and handling of the device easy.

10 The dosing apparatus of the present invention for
sterile and/or pharmaceutical solutions is of medical or
pharmaceutical application, for human or veterinarian use.

FIELD OF THE INVENTION

As is already known, in some situations it is an
15 advantage to dispense fix amounts of solution on localized
points, for curative or preventive purposes. These functions
are performed through conventional means such as syringes or
the like, working by sucking up liquids from a sterile
container through also sterile means, such as syringes, and
20 pouring out their collected contents on specific points of
the human or animal body.

This solution involves several problems, among
them, the transfer from a medium to another, since although
both mediums are sterile it usually presents problems of
25 sterility loss, as well as certain nuisances in its use and
handling.

BACKGROUND OF THE INVENTION

Devices containing pharmaceutical and veterinarian
liquid solutions are known, such as blisters, cartridges or
30 the like, which are provided with needles with means for
their coupling, which allow a direct use of them in its
administration.

A device of this kind is described in Spanish
patent No. 8801006, comprised of a container made of a
35 flexible synthetic material, its contents being poured out
through a pressure made against the walls thereof.

More concrete antecedents of the present invention

in the sector where the latter applies are in the first place US patent No. 2,319,383 by Merck & Co., Inc and in particular the embodiment disclosed in US patent No. 3,989,045 by William F. Van Eck, wherein a syringe is described comprised
5 of a container and a needle, the said container being balloon-shaped and with flexible walls, having fastening means on the container's neck.

The device referred to has a first disadvantage in its use, since it lacks a flat base for its physical
10 positioning on a surface, involving that the tip of the needle comes into contact with the surface where it lies, thus, losing its sterility.

Also in the referred position, part of the solution is poured out on the flat surface where the set lies, due to
15 capillarity.

Thirdly, it exists a high lack of precision when the container is being poured out, since the necessary flexibility of the container wall requires a substantial firm hand to dose with accuracy.

Other antecedents of the invention are found in British patent No. 1 573 514 by AB Helinos from Sweden, and German patent No. 29 00 827 by Merck Patent GmbH, in which devices are described comprising a flexible closed sealed container with a solution, said container being applied
25 against rigid elements provided with a needle that goes through it, being capable of puncturing by one of the needle ends the referred container and fittingly secure it, while the other end of the needle allows the exit of the contained solution.

These devices have the common disadvantage of requiring a coupling operation, situation that involves a manual (in the Merck solution) handling of the container and the rigid element for the end to be punctured to the former, thus, losing optimal conditions of tightness of the set, and
35 consistently, its sterility.

Like in abovementioned solutions, the lack of precision is also high when the container is being poured

out, mainly in the Merck solution.

Lastly, systems of cartridges containing solutions coupled to rigid structures are also known, such as that described in PCT patent WO 89/02286 by Wolke, in which a
5 device is described comprising a sealed container placed into a hollow rigid structure, with one of its ends provided with a needle which punctures and connects the solution which is contained into the container with the outside, being doseable through a plunger placed in the other end of the cited hollow
10 rigid structure.

Although this solution has a better reliability as for precision in the pouring out of the container contents, it also requires a manual handling of the containers to be placed into the hollow rigid structure.

15 Another important disadvantage is the high amount of pieces involved in the cited device, with a high cost in its production.

SUMMARY OF THE INVENTION

The device according to the present invention
20 eliminates the abovementioned disadvantages, succeeding in dosing and dispensing a sterile solution in optimal conditions, with an easy handling and high precision, as well as involving a low manufacturing cost.

For this aim, the present device comprises a
25 container with a solution, comprising:

- a- a flexible generally cylindrical laminar body with its wall bellow-shaped, with one of its bases blind and the other axially extended by a cylindrical tube ending in an outer ring,
- 30 b- a cylindrical tubular nozzle, which has a flat outer surrounding rim and having an end like a bevel edge, and its outer diameter being slightly smaller than the one of the orifice of the cylindrical tube which extends the bellows,
- c- a cup which covers part of the nozzle, having in its wall
35 a surrounding weakened line, and its mouth being extended by a flange, lying on the surrounding rim of the nozzle, and,
- d- a fluted ring which comprises a circular channel capable

of perimetrally trapping the ring of the extension of the body a) with the flange of the cup, said fluted ring being laterally extended by, at least, a lug.

5 The coupling between the flexible laminar body and the tubular nozzle is achieved by inserting the end of the latter in the orifice of the cylindrical tube which extends the bellow-shaped container. Likewise, the cup covers the other end of the nozzle, its flange lying on the outer ring of the flexible laminar body.

10 The described assembled elements are fixed by the fluted ring which perimetrally traps the ring of the flexible laminar body extension with the flange of the cup.

The described set is held on a rigid structure, as a support, comprising:

- 15 - a flat U-shaped surface with two non-contiguous and parallel ends provided with a L-shaped projection, determining two longitudinal and parallel guides,
- an axis perpendicularly connected underneath said flat surface and symmetrically disposed on it,
20 - a circular base which comprises a central recess, with a lateral extension provided with a passing hole, where the perpendicular axis is socketed, and with a lower extension held by pressure means perpendicular to said axis.

25 The axis perpendicular to the flat surface of the rigid structure may have a graduated scale.

The features of the aforesaid elements will be following described in detail.

DESCRIPTION OF THE DRAWINGS

30 The annexed drawings, only as an example, will help to better understand the invention, its characteristics and the advantages it provides.

Figure 1 is a perspective view of the flexible laminar body, the tubular nozzle and the cup, with the elements uncoupled,

35 Figure 2 is a cross section view of the elements shown in the figure 1, coupled and with the fluted ring that ties them together,

Figure 3 shows two views of a valve in section and in perspective with the three elements thereof,

Figure 4 is a perspective view of the support structure of the set shown in the Figure 1,

5 Figure 5 is a cross section view of the support structure, and,

Figure 6 is a perspective view of the support structure holding the set shown in figure 2,

The items designated with numbers on the drawings
10 correspond to the parts pointed out below.

PREFERRED EMBODIMENT OF THE INVENTION

In Figure 1 is shown a device according to the present invention, comprised of a laminar body (10), a nozzle (20) and a cup (30), illustrated in an uncoupled position,
15 on a same ideal axis.

The laminar body 10, the nozzle 20 and the cup 30, preferably made of plastic material, are obtained by moulding.

The laminar body 10 in its lower part has a
20 cylindrical general configuration, with its lateral wall 11 bellow-shaped and one of its bases blind. Its other base axially extends by a cylindrical tube 12, ending in an outer ring 13 which defines a central orifice 14 communicating through the tube 12 with the hollow body 10.

25 The nozzle 20 is tubular, with a longitudinal passage 21, having a cylindrical general configuration, with a flat outer surrounding rim 22.

The nozzle 20 of the figure 1 has an upper bevelled end 23. Such as it will be described below, this end may have
30 several forms according to applications.

The general diameters of the nozzle 20, both upper and lower with regard to the surrounding rim 22, are slightly lower than the one of the central orifice 14 and the one of the cylindrical tube 12 of the laminar body 10.

35 Such as abovementioned, the nozzle 20 is preferably made of plastic material. However, its width must provide such a rigidity that eliminates any possible flexibility

when handling.

The cup 30 is generally long-shaped, with a central cylindrical hollow section from which laterally two diametrically opponents lugs 31 and 32 emerge, with its upper
5 ends slightly inclined ending adjacent to the end of the cup.

Internally, the cup 30 is provided with a blind cylindrical cavity, not shown in Figure 1, with a slightly greater diameter than the one of the upper section of the nozzle 20.

10 In the lower part, the cup 30 comprises in its outer wall a surrounding weakened line 33, its mouth being extended by a flange 34 which defines a flat ring.

The internal cavity of the cup 30 may receive inserted the upper end of the nozzle 20, thus coinciding the
15 upper area of the surrounding rim 22 against the lower area of the flange 34 which defines the opening of the cup 30.

In the same way, the lower section of the nozzle 20 can be inserted through a central orifice 14 and penetrating into the cylindrical tube 12, thus coinciding the
20 lower area of the surrounding rim 22 with the upper area of the outer ring 13 of the body 10.

Figure 2 shows in cross section the body 10 and the cup 30 with the nozzle 20 inserted into the cylindrical tube 12, and in its turn into the cup 30.

25 In the same Figure 2, the fluted ring 40 is shown, defining a circular channel 41 perimettrally trapping the outer ring 13 of the body 10, with the flange 34 and the cup 30, and thus the surrounding rim 22 of the nozzle 20.

The fluted ring 40 is laterally extended by a lug
30 42 in the illustrated example.

The fluted ring 40 allows to hold together the body 10, the nozzle 20 and the cup 30 in a steady way.

In an industrial application of the device according to the present invention, it is better to first
35 fill up the body 10 with a solution before assembling the parts thereof.

Once said elements are assembled on the body 10,

the fluted ring will allow, apart from interconnecting the parts, to keep tight the inside of the device, the set being able to be sterilized by conventional means beyond the present invention.

5 The described device consist of a disposable closed container which allows to dispense solutions. So as to open the device and proceed to dose its contents the device shall be held with one hand taking its lug 42 and the other hand holding the cup 30 in order to proceed to its tearing by an
10 axial spin. In this operation both lugs 31 and 32 of the cup 30 efficiently cooperate, avoiding that the fingers may slip during the opening of the device.

Later, and with only one hand, the contained
15 solution may be dosed, by holding with two consecutive fingers of the hand the cylindrical tube 12 and pressing the blind base of the body 10 with the thumb. The lateral wall 11 of the body will give, allowing to dose by a slightly weakening of the bellows, and/or suck up by its recuperation.

The upper end 23 of the nozzle 20 shows a bevelled
20 form, for specific applications with regard to the use of the device. Such as abovementioned, the nozzle 20 may have different upper ends 23, as the one shown in Figure 3. Likewise, the inner tube which goes through the nozzle 20 may be provided with elements which allow to keep an
25 unidirectional passage of the solutions contained into the body 10.

In the Figure 3 a nozzle 20 which has in its upper part a cylindrical end 23 is shown.

The shown nozzle 20 is comprised of the connection
30 of two halves, upper and lower, having an orifice 21 which leads to a tubular inner tube 28 that goes longitudinally through it, with a disc 29 which is placed into a cavity 27, working as a valve, allowing an unidirectional passage of the solutions. The cited valve is conventional beyond the present
35 invention with regard to its particularities, different kinds of valves can be used.

Such as abovementioned, the ends 23 of the nozzle

20 may have different shapes according to the specific application of the solution to be dosed. Independently, several valves or direct tubes can be used into the nozzle 20.

5 The application of a one-way valve as described above allows to take out the air which may be in the body 10 and keep this position in a steady way. Similarly said valve stops any possible suck, and in its turn, penetration of other liquid or gaseous material into the body 10.

10 The nozzle 20 may also have the most convenient shape to be able to tightly secure coaxially to its outer surface conventional tubes or couplings in order to assure their retention. In all cases, the blind cavity of the cup 30 has a suitable shape in order to secure cited ends and in 15 its turn to generally keep tight the device.

 The fluted ring 40 is laterally extended by a lug 42. The device may have a multiple number of lugs.

 This cited lug has pertinent functional applications, allowing to adhere a label with the 20 identification of the solution which is contained into the device, such as a description, a formula, expiring date or the like.

 Apart from the abovementioned function, in order to facilitate the opening of the device, the use of a lug 25 allows to protect the fingers of the hand when the solution is being dosed avoiding the contact of them with the area receiving the solution.

 Likewise, when the device is not being used, the lug prevents the device from rolling over apparently flat 30 areas, and in its turn helps to keep the end 23 of the nozzle 20 apart from the very surface where the device is placed.

 The device described can be used alone or together with a rigid support.

 The Figures 4 and 5 show a rigid support 50. In the 35 Figure 6 is shown the rigid support 50 at which the dosing device has been socketed.

 In the rigid support 50 a flat surface 51 is

provided with one of its edges having an inlet 54, and with two non-contiguous and parallel ends provided with L-shaped projections 52 and 53 which define two longitudinal guides.

The rigid support 50 comprises an axis 33
5 perpendicularly connected underneath the flat surface 51, symmetrically arranged on cited surface.

In the lower part, the support 50 comprises a base 56 having a circular surface with a central recess 57 and a lateral passing hole 58.

10 The lateral passing hole 58 of the base 56 is slightly greater in diameter than the one of the axis 55.

The base 56 in its lower part has an extension with an inner passage 65 perpendicular to the lateral passing hole 58 and communicating with it. Pressure means constituted by
15 a screw 59 which controls a spring 61 are located within said passage and in its turn the latter fits on the cylinder 60.

Once the base 56 is placed in the axis 55 through its lateral orifice 58, the cylinder 60 presses by the assistance of the cited means on the previous paragraph on
20 the surface of the axis 55. So, the base 56 can only be slidable along the axis 55 when desired.

The base 56 on the axis 55 is in its upper part limited by the flat surface 51, and in its lower part by the inlet 62, which has in its last end a slight step against
25 which the cylinder 60 fits.

The outer surface of the axis 55 has a graduate scale 63, whose use will be describe below.

The different parts which comprise the rigid support can be also obtained by moulding, made of plastic or
30 metallic materials.

The dosing device is coupled to the rigid support 50. For doing so, the lug 42 has to be placed on the flat surface 51 with the assistance of the L-shaped projections 52 and 53 by securing the edges of the lug 42. In this
35 position, the neck 12 of the body 10 and the ring 40 are placed into the inlet 54. Inferiorly, the blind base of the body 10 is placed on the central recess 57 of the base 56 of

the rigid support. The Figure 6 illustrates the last positioning of the device in the rigid support.

The opening and handling of the dosing device coupled to the rigid support is identical to what described
5 above without it.

The application of the rigid support have clear advantages allowing to dose with greater precision, since it assists with a greater rigidity of the device set, and by having a graduate scale 63 on the axis 55. So, specific
10 amounts of solution can be dosed.

CLAIMS

1. Dosing device for sterile and/or pharmaceutical solutions, of the type consisting of a container which contains the solution and that is provided with outlet
5 connecting means, and a rigid support at which the said container is coupled, characterized by having the following parts:

- 10 a) a flexible generally cylindrical tubular body with its wall bellow-shaped, with one of its bases blind and the other axially extended by a cylindrical tube ending in an outer ring,
- 15 b) a cylindrical tubular nozzle, which has a flat outer surrounding rim having one of its ends bevelled and its outer diameter being slightly smaller than the one of the orifice of the cylindrical tube which extends the bellows,
- 20 c) a cup which covers the nozzle, having in its wall a surrounding weakened line, and being its mouth extended by a flange, lying on the surrounding rim of the nozzle, and,
- 25 d) a fluted ring which defines a circular channel capable of perimetally trapping the ring of the extension of the body a) with the flange of the cup, and said fluted ring being laterally extended by at least a lug.

2. Dosing device for sterile and/or pharmaceutical solutions, according to claim 1, characterized in that it further includes a one-way valve which may be placed between the bellow-shaped body and the nozzle.

30 3. Dosing device for sterile and/or pharmaceutical solutions, according to claims 1 and 2, characterized in that the end of the nozzle finishes in a bevelled tip.

4. Dosing device for sterile and/or pharmaceutical solutions according to claims 1 and 2, characterized in that
35 the very end of the nozzle is capable of ending in a conus of the 'Luer' type.

5. Dosing device for sterile and/or pharmaceutical

solutions, according to aforementioned claims, characterized by having, in a second embodiment, the following parts:

- 5 a) a flexible generally cylindrical tubular body with a bellow-shaped wall, with one of its bases blind and the other axially extended by a cylindrical tube ending in an outer ring,
- 10 b) a cylindrical tubular nozzle, which has a flat outer surrounding rim having one of its ends bevelled and its outer diameter being slightly smaller than the one of the orifice of the cylindrical tube which extends the bellows,
- 15 c) a cup which covers the nozzle, having in its wall a surrounding weakened line, and being its mouth extended by a flange, lying on the surrounding rim of the nozzle, and,
- 20 d) a fluted ring which defines a circular channel capable of perimetally trapping the ring of the extension of the body a) with the flange of the cup, and said fluted ring being laterally extended by at least a lug.
- 25 e) a rigid support capable of socketing the cited set, which is provided with:
 - a flat U-shaped surface with two non-contiguous parallel ends provided with a L-shaped projection,
 - 30 defining two longitudinal parallel guides,
 - an axis perpendicularly connected underneath said flat surface and symmetrically disposed on it,
 - a circular base which comprises a central recess, with a lateral extension provided with a passing hole, where the perpendicular axis is socketed, and with a lower extension held by pressure means perpendicular to said axis.

6. Dosing device for sterile and/or pharmaceutical solutions, according to claim 5, characterized in that the axis perpendicular to the base of the rigid support may have a graduate scale.

FIG.1

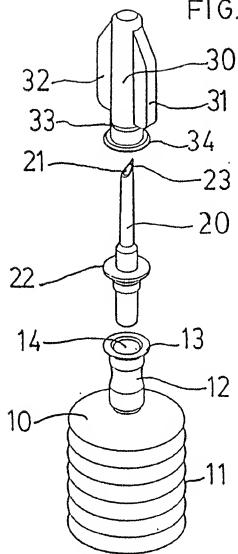


FIG.2

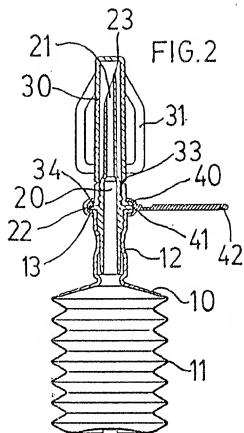


FIG.3

